

ENTERED

March 22, 2016

David J. Bradley, Clerk

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**UNITED STATES OF AMERICA
ex rel. JOHN KING and
TAMMY DRUMMOND, *et al.*,
Plaintiffs,

v.

SOLVAY S.A., *et al.*,
Defendants.§
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CIVIL ACTION H-06-2662

ORDER

Pending before the court is a motion to exclude the expert testimony of Richard A. Mortimer filed by relators John King and Tammy Drummond (the “Relators”). Dkt. 495. Having considered the motion, response, reply, and applicable law, the court is of the opinion that the motion should be DENIED.

I. BACKGROUND

The instant motion relates to whether the court should exclude or limit expert testimony by Dr. Richard Mortimer, who has a Ph.D. in economics with a concentration in industrial organization and international economics from the University of California, Berkeley. Dkt. 495 (motion to exclude); Dkt. 546, Ex. 1 (Mortimer’s curriculum vitae). SPI hired Mortimer to evaluate the opinions of Relators’ economist, Dr. Meredith Rosenthal, and to testify regarding any flaws in Rosenthal’s methodology. Dkt. 546 at 1. Relators filed the instant motion seeking to limit Mortimer’s testimony. Dkt. 495. Relators specifically request that the court preclude Mortimer from testifying about (1) the impact of off-label promotion on sales; (2) epidemiological observations such as prevalence of hypogonadism and hypogonadism as an underdiagnosed condition; (3) medical or

clinical opinions; and (4) legal opinions regarding *Bornstein* considerations,¹ what constitutes a false claim, and the substance of state prior authorization policies and regulations. Dkt. 495 at 22. SPI contends that (1) Mortimer is qualified; (2) his testimony is within the scope of his expertise; (3) his testimony regarding the impact of sales, prevalence of hypogonadism, and comorbid conditions is reliable; and (3) Mortimer will not offer legal opinions. Dkt. 546. The argument regarding the prevalence of hypogonadism relates to the drug AndroGel, and all claims relating to AndroGel have been dismissed because they are barred by the False Claims Act's Public Disclosure Bar. *See* Dkts. 386, 585. The court will thus address only whether Mortimer is qualified, whether his opinions relating to the impact of sales and comorbid conditions are reliable, and whether he expresses any impermissible legal conclusions.

II. LEGAL STANDARD

The Supreme Court of the United States acknowledged in *Daubert v. Merrell Dow Pharmaceuticals* that Federal Rule of Evidence 702 serves as the proper standard for determining the admissibility of expert testimony. *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 597–98, 113 S. Ct. 2786 (1993). Rule 702 provides:

A witness who is qualified as an expert by knowledge, experience, training, or education may testify in the form of an opinion or otherwise if:

¹ The *Bornstein* case is a U.S. Supreme Court False Claims Act case in which the Court considered how to calculate double damages under the False Claims Act and determined that “damages should be doubled before any compensatory payments are deducted, because that method of computation most faithfully conforms to the language and purpose of the Act.” *United States v. Bornstein*, 423 U.S. 303, 314, 96 S. Ct. 523 (1976). The Court noted that “this method of computation comports with the congressional judgment that double damages are necessary to compensate the Government completely for the costs, delays, and inconveniences occasioned by fraudulent claims.” *Id.* at 315.

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods;
- and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Under *Daubert*, a trial court acts as a “gatekeeper,” making a “preliminary assessment of whether the reasoning or methodology properly can be applied to the facts in issue.” *Daubert*, 509 U.S. at 592–93; *see also Kumho Tire v. Carmichael*, 526 U.S. 137, 147, 119 S. Ct. 1167 (1999); *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 243–44 (5th Cir. 2002). *Daubert* and its principles apply to both scientific and non-scientific expert testimony. *Kumho Tire*, 526 U.S. at 147. Experts need not be highly qualified to testify, and differences in expertise go to the weight of the testimony, rather than admissibility. *Huss v. Gayden*, 571 F.3d 442, 452 (5th Cir. 2009). Nonetheless, courts need not admit testimony that is based purely on the *ipse dixit* of the expert. *Gen. Elec. Co. v. Joinder*, 522 U.S. 136, 146, 118 S. Ct. 512 (1997); *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998).

In addition to being qualified, an expert's methodology for developing the basis of his or her opinion must be reliable. *Daubert*, 509 U.S. at 592–93; *Moore*, 151 F.3d at 276. “The expert's assurances that he has utilized generally accepted scientific methodology is insufficient.” *Moore*, 151 F.3d at 276. Even if the expert is qualified and the basis of her opinion is reliable, the underlying methodology must have also been correctly applied to the case's particular facts in order for her testimony to be relevant. *Daubert*, 509 U.S. at 593; *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 352 (5th Cir. 2007). The party proffering expert testimony has the burden of establishing

by a preponderance of the evidence that the challenged expert testimony is admissible. *See* Fed. R. Evid. 104(a); *Moore*, 151 F.3d at 276. The proponent does not have to demonstrate that the testimony is correct, only that the expert is qualified and that the testimony is relevant and reliable. *Moore*, 151 F.3d at 276.

III. ANALYSIS

A. Qualification

Relators argue that Mortimer is not qualified to offer opinions on subjects other than economics, and they take issue with his opinions that relate to having a clinical or medical understanding of the three drugs at issue and epidemiological data. Dkt. 495 at 2. SPI argues that Mortimer is qualified to testify about economics relating, specifically, to the healthcare and pharmaceutical industry and, even if he did not specialize in this area, the lack of specialization would go to the weight of his testimony rather than its admissibility. Dkt. 546 at 8.

Mortimer has a Ph.D. in economics and focuses on industrial organization. Dkt. 495 at 4 (citing Dkt. 495, Ex. B at 11). He has specifically studied in the area of healthcare, pharmaceuticals, and medical devices for over a decade and has published in these areas as well. Dkt. 495, Ex. B at 11–12. Mortimer testified that he considers himself “an expert in the application of economics in the area of healthcare and health policy.” Dkt. 495, Ex. B at 12.

The court has reviewed Mortimer’s curriculum vitae and finds that Mortimer is qualified to testify about economics and to opine about economics as it relates to the healthcare industry. *See* Dkt. 548, Ex. 1 (Mortimer’s curriculum vitae). The specific opinions that Relators highlight as being inappropriate are Mortimer’s calculation of the prevalence of hypogonadism from several epidemiological studies, his attempt to interpret medical literature to determine “unmet needs” that

the three drugs at issue may have been prescribed for that Rosenthal did not consider, and his discussion of comorbid conditions. Dkt. 495 at 17–18. The hypogonadism opinion is of no consequence since all claims related to AndroGel have been dismissed.

Mortimer’s opinions with regard to “unmet needs” and comorbid conditions have to do with his conclusion that Rosenthal may not have considered all the reasons physicians may have prescribed the drugs at issue that do not relate to off-label promotion. Whether Rosenthal considered all variables that could impact her conclusion is a valid economic inquiry. That being said, Mortimer is not a physician or clinical expert, so it would be inappropriate for him to testify about conclusions he personally drew from medical studies. However, if SPI lays the proper foundation with clinical experts at trial, Mortimer may testify about how economists generally would consider these outcomes in their calculations.

B. Reliability

Relators question the reliability, or lack thereof, of Mortimer’s methods. Dkt. 495. When asked during his deposition, for instance, whether he had undertaken any analysis regarding the impact on sales of advertising related to Relators’ off-label claims, Mortimer testified that he had not studied or undertaken any specific analysis to identify the impact of advertising on sales. *Id.* (citing Dkt. 495, Ex. B at 164).

SPI contends that Mortimer did not use his own independent methodology because he was serving as a rebuttal expert to Relators’ economics expert, Dr. Meredith Rosenthal, and Mortimer’s role as a rebuttal expert is to critique Rosenthal’s methodologies rather than undertake his own independent analysis. Dkt. 546 at 12–13. SPI points out that it is Relators’ burden, not SPI’s, to prove causation and damages. *Id.* at 13. SPI notes that Mortimer states in his response that the

purpose of his testimony is to “‘evaluate the report submitted and opinions expressed by Relators’ expert Meredith Rosenthal.’” *Id.* at 14 (quoting Dkt. 495, Ex. A).

What is important here is what Relators have *not* argued. Relators are concerned that Mortimer did not undertake his own independent analysis, but they have not argued that the variables Mortimer highlights in his critique of Rosenthal’s analysis are not scientifically valid considerations. *See Daubert*, 509 U.S. at 592 (instructing courts considering the admissibility of scientific evidence to consider whether a theory or technique has been tested, whether it has been subjected to peer review and publication, and whether it is generally accepted in the scientific community). The court finds that it was not necessary for Mortimer to undertake his own independent analysis and that his expertise regarding the types of variables economists should consider will assist the trier of fact.

C. Legal Opinions

Relators contend that Mortimer impermissibly offers legal opinions about trebling damages, what constitutes a false claim, and state prior authorization policies and regulations. Dkt. 495 at 19–22. SPI agrees that Mortimer may not render conclusions of law. Dkt 546 at 21. SPI contends, however, that Mortimer does not offer any legal conclusions. Instead, SPI asserts that Mortimer used the legal framework of the Medicaid statute to conclude that rebates impact the price of every prescription and that rebates should have been included in Rosenthal’s damages calculations. *Id.* at 22. As far as Mortimer’s considerations regarding what constitutes a false claim, SPI notes that Mortimer merely relies on this court’s conclusions in previous orders in this case. *Id.* at 23–24. With regard to the contention that Mortimer offers legal opinions regarding state prior authorization policies and regulations, SPI states that “Mortimer will not opine as to whether Aceon, AndroGel, or Luvox would or would not have been added to prior authorization lists in varying states.” *Id.* at


25. SPI contends that Mortimer merely notes that Rosenthal failed to account for these variations, which SPI argues economists offering rebuttal opinions are allowed to do. *Id.*

The court agrees with SPI that Mortimer's opinions regarding whether Rosenthal should have considered the impact of prior authorization in her calculations and his opinion regarding false claims do not rely on impermissible legal conclusions. As far as the opinions relating to damages, the court will determine the appropriate method for calculating damages prior to trial and will limit expert testimony to the appropriate legal framework at that time.

IV. CONCLUSION

Relators' motion to exclude the testimony of SPI's expert Mortimer is DENIED. However, Relators may reassert concerns regarding potential legal conclusions relating to damages calculations at the pretrial conference.

Signed at Houston, Texas on March 22, 2016.



Gray H. Miller
United States District Judge